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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/667,710

Applicant(s)

BAVARO ET AL.

Examiner

Christopher P. Bruenjes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 12-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20030922, 20050519, 20050718.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to radiopaque marker, classified in class 428, subclass 36.9.
- II. Claims 12-17, drawn to a method of making a radiopaque marker, classified in class 264, subclass 500.
- III. Claims 18-26, drawn to a method of marking a medical device, classified in class 156, subclass 80.
- IV. Claims 27-34, drawn to device for measuring lesion sizes, classified in class 604, subclass 529.
- V. Claims 35-45, drawn to a radiopaque, elastomeric composition, classified in class 524, subclass 406.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant

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case the product as claimed can be made by a materially different process such as forming the radiopaque composition and injection molding a tubular object having the preselected length.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process such as placing the radiopaque over an object to perform as a radiation shield to the object.

4. Inventions I and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a radiation shield or radiopaque marker applied directly to a balloon catheter and the inventions are

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deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

5. Inventions V and I are related as mutually exclusive species in an intermediate-final product relationship.

Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a composition for forming bullets and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

6. Inventions II and III are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the two processes have materially different functions, because one invention is a process of making an article and the other is a process of using that article.

7. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of

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the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as forming the radiopaque composition and injection molding a radiopaque marker having the preselected length.

8. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product or composition can be used in a materially different process such as forming a bullet.

9. Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant

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case the product as claimed can be made by another process such as adhesively bonding a radiopaque marker to the guidewire.

10. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product or composition can be used in a materially different process such as forming a bullet.

11. Inventions V and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a composition for forming bullets and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

12. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in

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the art in view of their different classification, restriction for examination purposes as indicated is proper.

13. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

14. During a telephone conversation with Gunther Hanke on April 4, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Specification

16. The use of the trademarks PEBAX, PELLETHANE, HYTREL, SANTOPRENE, KRATON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. For more information see MPEP 608.01(v).

Claim Objections

17. Claim 5 is objected to because of the following informalities: "MA-g-PO" should be written out because it is unclear if MA-g-PO is definitely maleic anhydride grafted polyolefin. Appropriate correction is required.

Claim Rejections - 35 USC § 112

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, the limitation "Pebax" renders the claim vague and indefinite because it is a trade name or trademark, which cannot be used properly to identify any particular material or product. See MPEP 2173.05(u).

Claim 5 recites the limitation "said multi-functional polymeric additive" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. It is assumed from the specification that this limitation is referring to the wetting agent and therefore it is suggested that the limitation be changed to "said wetting agent".

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the

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effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

21. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Elliott (US 2003/0164063 A1).

Regarding claims 1, 4 and 5, the preamble "radiopaque marker" is given little patentable weight for two reasons. First, it appears the preamble is reciting purpose or intended use of the claimed article, which would only be given weight with regard to any structural difference the intended use results in. Second, if the preamble is not merely reciting purpose or intended use the only structural limitation provided by "radiopaque marker" is an article that is opaque to radiation, such as x-rays. This limitation would cover any article as long as it is opaque to radiation. The article of Elliott is a radiation-shielding article (p.3, paragraph 56) and therefore anticipates the structural limitations provided by the preamble. The article of Elliott comprises a polymer such as Pebax and radiopaque particles such as tungsten disposed within said polymer and a wetting agent for facilitating encapsulation of said particles such as a wax, fluoropolymer or chemically modified polyethylene such as Fusabond from DuPont (p.5, paragraphs 88-93 and Table 2 on p.6), which is maleic anhydride grafted polyethylene. The tungsten have an average diameter of

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at least 2 microns and a maximum diameter of about 20 microns, as shown by the particle size distribution (p.6, paragraph 94).

Regarding claims 2 and 3, the volume percent of tungsten in the article is greater than 18 volume percent and approximately 36 volume percent, when determined based on the weight percent and densities of the components of the article presented in Table 2 on page 6.

Regarding claims 6-8, the limitations that the particles are produced by a pusher process or by an atomization process are given little patentable weight in an article claim. Although all limitations are considered, process limitations in an article claim are only given weight insofar as the structural differences the process teaches. In this case, because the radiopaque particles are substantially equiaxed as shown by the particle size distribution (p.6, paragraph 94), the structural differences provided by the processes of forming particles that are substantially equiaxed are taught by Elliott.

Regarding claim 10, Pebax is thermoplastic.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott (US 2003/0164063 A1).

Regarding claim 9, Elliott teaches all that is claimed in claim 1 as shown above, but fail to teach that the article further comprises an antioxidant. However, it is well known in the art that antioxidants are added to elastomers in order to improve prevent oxidative decomposing, and therefore have longer stability and life. Therefore, it would have been obvious to one having ordinary skill in the art to add an antioxidant to an article formed of Pebax in order to increase the stability and

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life of the article, since antioxidants prevent oxidation and decomposition caused by oxidation.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add an antioxidant to the article of Elliott, since it is well known in the art as a common additive to elastomers and would be added in order to prevent premature oxidation of the article.

Regarding claim 11, Elliott teaches all that is claimed in claim 1 as shown above, and teaches that the article is manufactured as a radiation shield. Elliott fails to teach that the article is necessarily formed to define a tubular structure. However, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that depending on the shape of the object the article of Elliott is providing a radiation shield to would determine the shape of the article of Elliott.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the radiation shield of Elliott to define a tubular structure when the object shielded from radiation has a tubular shape.

Conclusion

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25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Klein et al (USPN 5,776,141) teaches a similar radiopaque marker but fails to teach diameter of the radiopaque particles and a wetting agent. Also cited are: McMahon (USPN 6,994,723); Stoltze et al (USPN 6,059,738); Chiu et al (USPN 6,761,708); Boylan et al (US 2001/0049549 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

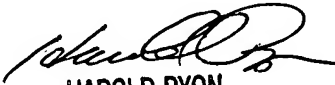
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB
June 10, 2006


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

6/12/06